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No. 99-1749

In The

Supreme Court of the United States

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

1. This Court has long understood that the line between what Congress must do itself and what it can delegate to an officer or agency of the Executive Branch "has not been exactly drawn," and so requires the "delicate and difficult inquiry" of the Court. *Wayman v. Southard*, 23 U.S. 1, 43, 46 (1825) (Marshall, C.J.). In *Clinton v. City of New York*, 524 U.S. 417 (1998), this Court drew such a line marking the boundary of legislative and executive power by holding the Line Item Veto Act to be a violation of the Presentment Clause. U.S. Const. art. I, § 7, cl. 2. In this case, the power of the Secretary of Health and Human Services (the "Secretary") to alter the Vaccine Injury Table (the "Table") established by the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act") crosses the line drawn in *Clinton*, and similarly, indeed more egregiously, violates the Presentment Clause.

In *Clinton*, this Court concluded that the vice of the line-item veto was that, through his "cancellation" of items in spending bills enacted by Congress, in "both legal and practical effect, the President . . . amended two Acts of Congress by repealing a portion of each," 524 U.S. at 438, but did not do so according to the procedures mandated by the Constitution, *id.* at 448. The Vaccine Act empowers the Secretary not simply to halt the operation of a statutory provision, but to affirmatively "modify" and "amend" the Table set out in the United States Code by act of Congress, as even the Court of Appeals for the Federal Circuit below conceded. Appendix to the Petition for a Writ of Certiorari ("App.") 19a. And, as in *Clinton*, the Secretary's amendment or modification of those statutory provisions was not accomplished according to the procedures required by the Constitution. Under *Clinton*, then, this power that the Vaccine Act gives to the Secretary is unconstitutional. Neither the Federal Circuit below, nor Respondent now, avoids this result by effectively distinguishing *Clinton* from the central issue here.

a. Before even mentioning *Clinton*, both the Federal Circuit and Respondent have tried to remove the Vaccine Act from Presentment Clause difficulty by claiming that the Secretary's promulgation of a Table to replace the one enacted by Congress is simply normal rulemaking and does not really amend a statute in any constitutionally significant way. This is so, they say, because the Secretary is simply "implement[ing] Congress's direction to issue regulations making appropriate adjustments to the Initial Table." Respondent's Brief in Opposition ("Opp.") at 12. *See also* App. 19a. Of course such a statement begs the question of whether those regulations unconstitutionally change a statute. Begging the question further, Respondent reminds us that, after all, Congress itself provided for these regulations to supersede its statutory Table. *See* Opp. at 12-13. That Respondent would offer such analysis, so obviously contradicting elementary principles of this Court's jurisprudence – indeed, of logic – underscores the need for this Court's attention to the issues raised by this case.

As we pointed out in our Petition for a Writ of Certiorari ("Pet."), the fact that the Secretary's action can be labeled "rulemaking" does not resolve the constitutional issue. *See* Pet. at 18. If such labels insulated the Secretary's acts from Presentment Clause scrutiny, her "rules" could effectively rewrite the U.S. Code, thereby rendering the Constitution's assignments of power a lawyer's charade. And the fact that Congress gave the Secretary this power to amend the statutory Table hardly answers the question of whether it was constitutionally permissible to do so. Congress also created the line-item veto mechanism struck down in *Clinton*. *See Clinton*, 524 U.S. at 452 (Kennedy, J., concurring) ("[O]ne Congress cannot yield up its own powers, much less those of other Congresses to follow.").

Respondent further argues that the only distinction between a garden-variety rulemaking and the Secretary's

regulatory change of the statutory Table is that Congress enacted the Table in the Vaccine Act itself. "That distinction," Respondent continues, "is not enough to turn an authorized rulemaking into a statutory 'amendment' that would require passage by Congress and presentment to the President." Opp. at 12. If this were true, then the Presentment Clause might never draw Chief Justice Marshall's line.[1]

As this Court in *Clinton* made clear, the Presentment Clause question is one of constitutional structure and procedure. *See Clinton*, 524 U.S. at 448-49 (explaining that the line-item veto of the President "is surely not a document that may 'become law' pursuant to the procedures designed by the Framers"); *id.* at 449 (Kennedy, J., concurring) ("The Constitution's structure requires a stability which transcends the convenience of the moment."). Contrary to Respondent's disparagement, the fact that an officer of the Executive Branch changes a provision of law enacted by Congress *is* central to the structural question raised by the Presentment Clause. It is possible that a Vaccine Act authorizing the Secretary to promulgate the initial Table and amend it via rulemaking would have passed muster under the Presentment Clause, as Judge Plager in dissent below suggested. *See* App. 39a. But that is not what Congress did. To accept Respondent's arguments would be to blur, if not erase, the structural line of the Presentment Clause.

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[1] If the Line Item Veto Act, instead of giving the President the power to "cancel" a spending item, had authorized the Director of the Office of Management and Budget to cancel by accelerated rulemaking a spending item enacted by Congress, would *Clinton* have been decided differently? Certainly nothing in the Court's opinion there indicates that an agency rule canceling the effect of a statutory provision would be any less offensive to the Presentment Clause than direct action by the President.

b. The Federal Circuit offered three grounds for distinguishing *Clinton* from this case, all three of which were drawn from *Clinton's* discussion of *Field v. Clark*, 143 U.S. 649 (1892). *See* App. 20a-22a. Respondent has reiterated those alleged bases for distinguishing the cases, but without explicitly relying on *Field*. *See* Opp. at 8-9, 14. Respondent's reticence is understandable, since *Field* involved an application of the nondelegation doctrine, not the Presentment Clause. *See Clinton*, 524 U.S. at 465 (Scalia, J., concurring in part and dissenting in part).

The limited assistance of these bases in resolving the Presentment Clause issue, due to the different focus of *Field*, is apparent. If the Secretary under the Vaccine Act exercises a "unilateral power to change the text of duly enacted statutes" in violation of the Presentment Clause, *Clinton*, 524 U.S. at 447, whether or not the requirements of the nondelegation doctrine are met – *i.e.*, whether the Secretary's actions were sufficiently constrained, whether that action was "based on the same conditions contemplated by Congress," and whether the action "contraven[ed] Congress's policy judgment," Opp. at 14 – is irrelevant. *See also* Pet. at 18-19 (further distinguishing *Field*). If the Secretary has *amended* the provisions of a statute, she has violated the Presentment Clause irrespective of why she did it or what guidance she followed in doing so.

Moreover, *Field* upheld an Executive Branch power far closer to the power at issue in *Clinton* – "the power to suspend an exemption from import duties," compared to "the power to cancel portions of a duly enacted statute," 524 U.S. at 443 – yet the *Clinton* Court nevertheless found that the line-item veto violated the Presentment Clause. The instant case arises from a far more extensive lawmaking power than the line-item veto, for the Secretary has promulgated as governing law her own "replacement" of Congress's statutory Table. *See* Opp. at 8. Respondent has made no effort to show how the *Field*

analysis, even if somehow shoe-horned into the Presentment Clause context, could possibly save the Secretary's Vaccine Act power under the Presentment Clause if it could not save the more modest line-item veto power in *Clinton*. Yet the Federal Circuit used the inapposite *Field* analysis to do exactly that, casting a cloud over what heretofore would have been the relatively clear scope of *Clinton*. Such trimming of a major, recent precedent of this Court surely calls for this Court's examination as a general matter, but particularly so here because, given the Federal Circuit's exclusive power to review Vaccine Act cases, that court's decision in this case will give a final imprimatur to the Secretary's expansive power to reshape this important program as she will.

2. With respect to the nondelegation argument generally,[2] Respondent simply reiterates the Federal Circuit's observation that the Vaccine Act contains "more-than-adequate 'substantive guideposts and procedural requirements' " to create an "intelligible principle" that governs the Secretary's creation of a replacement for the Congress's statutory Table. Opp. at 16 (quoting App. 23a). But, although the Vaccine Act does set out *procedures* for

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[2] Petitioner agrees with Respondent, *see* Opp. at 19 n.6, that there is no reason to defer review of this case pending the Court's decision in *Browner v. American Trucking Ass'ns*, 175 F.3d 1027 (D.C. Cir. 1999), *cert. granted*, 120 S. Ct. 2003 (May 22, 2000) (No. 99-1257). The District of Columbia Circuit's decision in that case addresses no Presentment Clause questions, and involves only a fairly unusual nondelegation issue in which the unconstitutional delegation of power might be remedied by "an interpretation without the constitutional weakness." 175 F.3d at 1038. As a result, the Court of Appeals remanded the case to the agency to permit it to make an interpretation not inconsistent with the nondelegation doctrine. The instant case, in contrast, involves not only an important Presentment Clause issue, but also a nondelegation claim that cannot be avoided by a limiting interpretation of the statute.

the Secretary to follow, Respondent has not shown how those procedures constitute "*substantive* guideposts." Pet. at 21-22 (emphasis added).

More specifically, the essential nondelegation problem in this case is the lack of congressional guidance as to how the Secretary should act when scientific knowledge neither confirms nor denies that a particular vaccine can cause a particular injury. *See* Pet. at 22-26. Respondent's answer to this argument begins with a mischaracterization of the facts, claiming, with citation to no supporting authority, that the Institute of Medicine ("IOM") Report concluded that "there was no credible evidence of prolonged neurological damage from . . . [DPT] vaccine." Opp. at 5. This is *not* what the IOM Report concluded. As the Secretary herself explained, her Table severely narrowed the scope of injuries eligible for compensation to acute encephalopathy because "[t]he IOM . . . concluded . . . that 'the evidence remains insufficient to indicate the *presence or absence* of a causal relation between DTP and chronic nervous system dysfunction under any other circumstances.' " 60 Fed. Reg. 7678, 7683 (Feb. 8, 1995) (quoting IOM Report Executive Summary) (emphasis added). Thus, the Secretary chose to exclude children from the Program where evidence of causation was uncertain, *see* Pet. at 24-26, in direct conflict with Congress's decision to structure the Vaccine Compensation Program to give claimants the "benefit of the doubt."[3]

Respondent acknowledges that Congress conferred authority on the Secretary in "broad terms" to amend the statutory Table, Opp. at 17, but then never addresses the issue of what guidance the Secretary has been given in

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[3] Respondent and the Federal Circuit are thus also quite wrong when they claim that the Secretary was not making a policy judgment different from that of Congress when she replaced the statutory Table with her own. *See* Opp. at 14; App. 22a.

the face of scientific uncertainty. Respondent simply says that "Congress presumably conferred regulatory authority in those broad terms because it understood that adapting the Initial Table, in light of developing scientific knowledge, would require the exercise of informed administrative judgment that might either increase or decrease the scope of presumptive, Table-based compensability." *Id.* Certainly, scientific conclusions that certain vaccines cause some and do not cause other injuries are the fruit of "developing scientific knowledge." As we noted in our Petition, if the Secretary amends the Table as a result of this developing knowledge, such a change arguably could be shaped by an "intelligible principle" in the Vaccine Act. Pet. at 23. But if the evidence of causation of certain injuries remains "insufficient" to establish the presence or absence of causation, "scientific knowledge" throws no "light" on the question of whether the children who have suffered those injuries should still be benefited by the Table mechanism. And such an administrative judgment cannot be "informed" by science when scientific knowledge has not developed far enough to provide an answer. Science does not guide the Secretary in her "thumbs up" or "thumbs down" in that circumstance. Nothing but her own, "uncanalized" policy preferences induced the Secretary to give a thumbs down on the injuries suffered by Petitioner Julie Terran. *See Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 675 (1980) (Rehnquist, J., concurring).

3. The error below concerning Petitioner's "off-the-Table" claim centers on the special master's conclusion that such claims must be measured "*under the same standards which apply in traditional tort litigation.*" App. 75a (emphasis in original). This error merits this Court's review because it fundamentally disrupts the unique, two-part standard of proof designed by Congress to award compensation under the Vaccine Act. *See* Pet. at 5, 7, 28. The confusion within the Federal Circuit centers not

on the standard of proof itself, which is directly set forth in the statute, but in the interpretation and application of one prong of this standard of proof: the provision that, to award compensation, there must *not* be a preponderance of the evidence that the claimed injury is due to factors unrelated to the administration of a vaccine. 42 U.S.C. § 300aa-13(a)(1)(B). As the Secretary has explained to the Court before, when the government cannot point to such identifiable factors, this provision "requires that the claimant receive the benefit of the doubt on the issue of causation." Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, *Shalala v. Whitecotton*, 514 U.S. 268 (1995) (No. 94-372), at 17.

Yet in this case, reflecting the split of understanding in the Federal Circuit that effectively renders this benefit of the doubt a nullity, *see* Pet. at 26-30, the special master rejected Petitioner's claim even though he concluded that her injuries were *not* caused by "any factor unrelated to the administration of the vaccine." App. 89a. This is not a fact-bound issue as Respondent claims, *see* Opp. at 19, but a legal error that has undermined the promise of the Vaccine Compensation Program as envisioned by Congress. It is not only appropriate, but vitally necessary to the operation of the Program, that this Court restore that promise.

4. Finally, it is worth noting that Respondent has essentially identified no true vehicle problems encumbering the Court's review of this case, instead engaging the issues raised squarely on the merits. In closing with a brief mention of two "factors that weigh against review," Respondent first notes that, should the Court grant review, it might disinter a procedural argument it lost before the Federal Circuit. Opp. at 19. Respondent does nothing more, however, than to state the accepted proposition that a party that has not filed a petition for certiorari may defend a judgment below on any ground that does seek alteration of that judgment. *See, e.g., Northwest*

Airlines, Inc. v. County of Kent, 510 U.S. 355, 364-65 (1994). This is true in every case reviewed by this Court and does not counsel against review in this particular case.

The Respondent goes on to summarily claim that the nonseverability clause in the Vaccine Act "counsels against granting review." Opp. at 20. Here again, if that clause counsels against this Court's review of the constitutional questions raised here, it will always do so, and no case could ever be a vehicle to address the serious constitutional issues that plague the operation of the Vaccine Act. In short, the nonseverability clause offers no basis to conclude that this case is not an appropriate vehicle by which the Court can resolve these critical matters.[4]

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[4] On the merits, if the nonseverability clause invalidates the whole Compensation Program upon a ruling for the Petitioner, then neither she nor any claimant can ever have standing to raise these constitutional issues. Such an absolute bar raises serious constitutional questions of its own, which this Court traditionally seeks to avoid through statutory construction. *See Johnson v. Robison*, 415 U.S. 361, 366-67 (1974); *Webster v. Doe*, 486 U.S. 592, 603 (1988); *Weinberger v. Salfi*, 422 U.S. 749, 762 (1975). Such a construction is readily available here because the nonseverability clause creates only a presumption against severability. *See, e.g., Dorchy v. Kansas*, 264 U.S. 286, 290 (1924); *United States v. Jackson*, 390 U.S. 570, 586 n.27 (1968). Declining to apply the presumption would not conflict with the purpose of the clause, which apparently was to ensure that, if the Vaccine Act's limitations on access to state courts and on tort liability were overturned on constitutional grounds, the Vaccine Act's unique compensation mechanism would also cease rather than leaving intact two separate avenues for compensating injured children. *See, e.g.*, 135 CONG. REC. S16,157 (daily ed. Nov. 17, 1989) (statement of Sen. Kennedy) (nonseverability clause ensures that "entire system of compensation and tort change would fall" if either provision fell). Moreover, the standing issues briefly noted by Respondent are hardly "difficult," Opp. at 20, since in any standing inquiry a plaintiff's merits claims,

CONCLUSION

For the foregoing reasons, and the reasons stated in the petition, the petition for a writ of certiorari should be granted.[5]

Respectfully submitted,

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which include the severability issue, are assumed to be true. *See Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (citing *Warth v. Seldin*, 422 U.S. 490, 500 (1975)); *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38 (1976); *Immigration & Naturalization Serv. v. Chadha*, 462 U.S. 919, 936 (1983).

[5] Respondent has submitted one Reply in Opposition to both our Petition for a Writ of Certiorari and to that filed in *O'Connell v. Shalala*, No. 99-1747. Though these cases raise the same constitutional issues, the Federal Circuit set out its opinion in this case, and ruled in *O'Connell* only by reference to its opinion here. *O'Connell* adds no additional facts that illuminate these issues, and thus the Court's consideration of them would not be significantly aided by plenary review of *O'Connell* in addition to this case. In our view, the Court should hold the petition in *O'Connell* pending the disposition of the petition in this case.